DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

94546d

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Stoneham, Massachusetts 02180
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WARNING LETTER
NWE-18-04W

VIA FED-EX
January 30, 2004

Mr. Charles P. Moser, Owner
World Health Products, LLC
64 Sunnyside Avenue
Stamford, CT 06902

Dear Mr. Moser:

The U.S. Food and Drug Administration (FDA) conducted inspections of your firm, World Health Products, LLC, located at 64 Sunnyside Avenue, Stamford, CT 06902 from June 4-12, 2003 and June 30-July 8, 2003. During these inspections, our investigators documented that you distribute products marketed with disease-related claims, and street drug alternative claims. Our investigators collected labeling, including promotional information from your firm's several websites, for many of your firm's products. A review of that labeling indicates serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act along with FDA's food, drug and dietary supplement regulations on the Internet through links on FDA's web page www.fda.gov.

Based on our review of product labels and claims for Fornatab, Happy Pills, and Liquid Relaxation on your firm's websites (see chart below), the labeling for your products bears claims that refer to the cure, mitigation, or prevention of disease:

Product	Websites
Fornatab	www.fornatab.com www.worldhealthproducts.com www.musclesoft.com www.liquidrelaxation.com/fornatab.php
Happy Pills	www.renewg.com/happypills.html www.germanamericantechnologies.com www.musclesoft.com
Liquid Relaxation	www.liquidrelaxation.com www.worldhealthproducts.com www.germanamericantechnologies.com www.musclesoft.com

Disease claims made for your products include the following statements:

Fornatab
"Fornatab contains highly absorbable, pharmaceutical-grade yohimbe, derived from a small evergreen tree native to Africa.... Yohimbe bark has been used for many decades...to treat men who are impotent."
"Chemically, Yohimbe bark contains a substance called yohimbine.... [T]he drug yohimbine is considered an effective for treatment for erectile impotence."

Happy Pills
"[T]reat depression, anxiety disorders...fibromyalgia, obesity, migraine headaches...."
The website www.renewg.com/happypills.html also lists the prescription anti-depressants Zoloft, Celexa, Wellbutrin, and Paxil and implies that Happy Pills are a safe non-prescription alternative to those drugs.

Liquid Relaxation
"[F]ight insomnia."
"Liquid Relaxation may be considered as safer alternative to Valium, Xanax, or other medications in this product catagory [sic]."

Furthermore, your Internet web sites for the products Liquid Relaxation and Renew G, from which these two products may be ordered, promote these products with claims indicating that they are intended as street drug alternatives, as follows:

Liquid Relaxation	www.liquidrelaxation.com www.worldhealthproducts.com www.musclesoft.com	"Liquid Relaxation may be considered as safer alternative to Valium, Xanax or other medications in this product catagory [sic]..."
Renew G	www.germanamericantechnologies.com www.musclesoft.com www.worldhealthproducts.com www.liquidrelaxation.com/renewg.php www.renewg.com	"...Awesome Ecstasy and GHB alternative..." "Within 15-20 minutes Renew G produces very strong euphoric feelings similar to GHB and ecstasy. Rolling and waving sensations last about 4 hours."

Street drug alternatives are not intended to supplement the diet, and therefore they are not dietary supplements. In March of 2000, FDA made available the document, "Guidance for Industry Street Drug Alternatives." A copy of this guidance document was given to you during the June 2003 inspection of your firm and is also available at the FDA Internet web site, http://www.fda.gov/cder/guidance/index.htm.

These disease and street drug alternative claims cause your products Fornatab, Happy Pills, Liquid Relaxation, and Renew G to be drugs as defined in Section 201(g)(1)(B) of the Act. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined by Section 201(p) of the Act. Under Section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application. Since these products are not the subjects of approved NDAs, they may not be marketed in the United States and their continued marketing violates Section 505(a) of the Act.

The labeling of your products Fornatab, Liquid Relaxation, Happy Pills, Renew G and German Stack indicates that you intend to market these products as dietary supplements. Even if your products Fornatab, Liquid Relaxation, Renew G and Happy Pills did not contain claims in their labeling that cause them to be drugs, they would be misbranded as dietary supplements.

As dietary supplements, Fornatab, Liquid Relaxation and German Stack are misbranded under Sections 403(i)(1) and 403(s)(2)(B) because the statement of identity does not include the term "dietary supplement" or other descriptive term authorized by 21 CFR 101.3(g).

Liquid Relaxation is misbranded within the meaning of section 403(i)(2) of the Act in that the ingredient Suntheanine® is not declared by its common or usual name, as required by 21 CFR 101.36(b)(3). In addition, the ingredient Novel Polyose Complex must be declared by its common or usual name under 21 CFR 101.36(b)(3).

Liquid Relaxation is further misbranded within the meaning of section 403(q)(5)(F) of the Act because the product label does not specify the total amount of the proprietary blend as required by 21 CFR 101.36(c) (although amounts of individual ingredients in the blend are not required). FDA requires that the dietary ingredients in a proprietary blend are to be listed in order of predominance by weight. Furthermore, the product violates 403(q)(5)(F) because the label lists ingredients in the "Supplement Facts" panel that are not dietary ingredients (i.e., triple filtered purified water, natural and artificial flavoring, high fructose corn syrup, citric acid, and sodium benzoate). These ingredients must be listed outside of the "Supplement Facts" panel as required by 21 CFR 101.4(g). In addition, Liquid Relaxation is misbranded under section 403(q)(5)(F) of the Act because the label does not list vitamins and minerals as individual ingredients as required by 21 CFR 101.36(b)(2) and (3).

Happy Pills is misbranded within the meaning of section 403(i)(2) of the Act in that the ingredient Suntheanine® is not declared by its common or usual name, which is required by 21 CFR 101.36(b)(3). Happy Pills is also misbranded under Section 403(i)(2) of the Act because it contains ingredients that are not declared on the label. The dietary ingredients listed in the "Supplement Facts" panel are contained in a capsule, but the capsule ingredients are not declared on the label in accordance with 21 CFR 101.4(g).

The products Liquid Relaxation, Happy Pills, and Renew G are misbranded under section 403(q)(5)(F) of the Act because the labels for these products do not separate dietary ingredients that have a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) (established by regulations in section 21 CFR 101.9(c)(8)-(9)) from declared dietary ingredients for which an RDI or DRV has not been established, as required by 21 CFR 101.36(b)(2), (b)(3), and (e). Further, the labels of these products do not provide information on the percent daily value for each dietary ingredient (either a percentage of the RDI or DRV or the statement "Daily Value not established," as applicable), as required by 21 CFR 101.36(b)(2)-(3).

Fornatab is also misbranded under Section 403(e) of the Act because the product label does not bear the address of the manufacturer, packer, or distributor in accordance with 21 CFR 101.5.

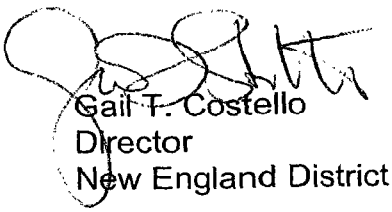
This letter is not intended to be an all-inclusive review of your products, labeling, and Internet websites. The violations described above are not intended to be an all-inclusive list of violations concerning your firm and its products. You are responsible for ensuring that all products marketed by your firm are in compliance with applicable United States laws.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Act provides for seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of the revised labeling should also be submitted. If corrective action cannot be completed within 15 working days, state the reason(s) for delay and the time at which the corrections will be completed.

You should direct your reply to Patricia Murphy, Compliance Officer at One Montvale Avenue, Suite 4, Stoneham, MA 02180. If you have any question concerning this letter, please contact Ms. Murphy at 781-596-7758.

Sincerely,



Gail T. Costello
Director
New England District

cc:

[redacted]